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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/148,973	09/04/98	GREENAMYRE	J PC10023A

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HM12/0928

EXAMINER

MACMILLAN, K

ART UNIT	PAPER NUMBER
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1618

6

DATE MAILED: 09/28/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/148,973

Applicant(s)

Greenamyre et al

Examiner

Keith MacMillan

Group Art Unit

1618



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-8 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3 and 5-7 is/are rejected.

☒ Claim(s) 4 and 8 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Priority

1. Applicants' claim to priority from provisional application 60/057,965, filed 9/5/97, is acknowledged. This information has not been entered into PTO databases as yet. Applicants may wish to file for a corrected filing receipt, therefore.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arnold et al, US patent 5,670,516.

Arnold et al teach a method of treating neurological disorders by administering a compound that blocks (or antagonizes) AMPA receptors. The claims differ in that they are drawn to treating a more specific neurological disorder, namely dyskinesia associated with dopamine agonist therapy (claims 1 and 5), wherein the therapy comprises administration of L-dopa or L-dopa in combination with an inhibitor of peripheral dopadecarboxylase (claims 2 and 6), wherein the peripheral dopadecarboxylase is cardidopa or benserazide (claims 3 and 7). It would have been obvious to one of ordinary skill in the art to use AMPA antagonists to treat dyskinesia, in

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view of the patent's entire disclosure, however, because Arnold et al teach that blocking AMPA receptors is an effective way to treat a variety of disorders, including dyskinesia. See for instance claims 24 and 29. One would have been motivated to do so with a reasonable expectation of success, because the patent teaches dyskinesia is among those neurological disorders responsive to AMPA antagonists. It is acknowledged that Arnold et al exemplify different AMPA antagonist compounds. However, instant claims 1-3 and 5-7 are not limited to particular AMPA antagonists.

Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klockgether et al, American Neurological Association, 1991 (of record in the IDS).

The reference teaches that blocking AMPA receptors (by administering AMPA receptor antagonists) may provide a new strategy for treating Parkinson's disease (PD). The claims differ because they are drawn to treating dyskinesia associated with L-dopa therapy. It would have been obvious to modify the process implied by Klockgether et al, however. One would have been motivated to do so for the following reasons: 1) Klockgether et al suggest treating PD patients who are on L-dopa therapy, as they suggest that AMPA antagonists can "potentiate" the actions of l-dopa, but reduce tremor associated therewith. (Page 18, column 2). 2) Klockgether et al suggest dyskinesia, because Parkinson tremor is the main symptom of PD that results in dyskinesia.

4. Claims 1-3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stella et al (American Neurological Association, 1996, of record in the IDS) in view of Klockgether et al, *supra*.

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Stella et al teaches administering glutamate antagonists to treat dyskinesias associated with l-dopa therapy in Parkinson's disease. The claims differ because they call for administration of an AMPA receptor antagonist as the glutamate antagonist. It would have been obvious to one of ordinary skill in the art to use AMPA antagonists as the glutamate receptor antagonist, rather than the NMDA receptor antagonist, however. One would have been motivated to make the substitution because Klockgether et al teach that both AMPA antagonists and NMDA antagonists are glutamate receptor antagonists. See page 1, column 2.

Allowable Subject Matter

5. Claims 4 and 8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 4 and 8 are limited to administration of 3-(2-chlorophenyl)-2-[2=(6-diethylaminomethyl-pyridin-2-yl)-vinyl]-6-fluoro-3H-quinazolin-4-one. This compound is not taught in the prior art, but rather appears for the first time in the literature in one or more of Applicants' own disclosures, all of which were published less than one year prior to the critical date. Thus, 3-(2-chlorophenyl)-2-[2=(6-diethylaminomethyl-pyridin-2-yl)-vinyl]-6-fluoro-3H-quinazolin-4-one was not known to be an AMPA receptor antagonist prior to the critical date.

6. Any inquiry concerning this communication should be directed to Keith MacMillan at telephone number (703) 308-4614.

Keith MacMillan

9/26/99


KEITH D. MacMILLAN
PRIMARY EXAMINER